# QPharma’s Medical Device Division Offers Guidance on UDI Final Rule

Business Wire

On Friday, September 20, the final Unique Device Identification (UDI) rule was issued by the Food and Drug Administration in conjunction with the 2013 UDI Conference in Baltimore, Maryland. Tom Beatty, Sr. Principal, UDI Compliance at QDevice, the medical device consulting division of QPharma, was in attendance for the announcement.

“In general, industry participants at the conference seemed pleased that their feedback regarding the draft rule was heard and considered by FDA,” noted Beatty.

In publishing the rule, which concerns the establishment of unique identifiers on medical device labeling, FDA introduced a number of key amendments to early drafts: The term “Compliance Date” replaces the term “Effective Date” used in the draft rule; The elimination of the requirement for direct imprinting of the UDI on implantable devices, allowing the code to be printed on the packaging rather than the device; The ISO 8601-aligned date standard will be used for UDIs; FDA may grant one-year extensions for specific Class III devices if it is deemed to be in the best interest of the public health; Inventories of medical devices manufactured prior to the final rule will be allowed to be sold without UDIs for a period of three years from the compliance date of the device; Class I devices that are sold via retail may use the product’s Universal Product (UPC) Code as its UDI; and Multiple single-use devices within multi-packs will only be required to print the UDI on the multi-pack and not the individual device. “With the highly anticipated release of the final rule, medical device companies must prepare to meet the many challenging compliance dates that have been set forth,” said Beatty. “Getting the right UDI on the right product at the right time is a complex and vital function, and we urge all device manufacturers not to delay in establishing their UDI compliance programs.”